WP+ 93U CRP-042 01/25/90

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kuberasampath et al. Examiner:

Serial No.: 422,613 Group Art Unit:

Filed: October 17, 1989 Attorney Docket: CRP-042

Title: BONE COLLAGEN MATRIX FOR IMPLANTS

COMMS. AND MAIL BOX AF 2/2/90

Honorable Commissioner of Patents and Trademarks
Washington, DC 20231

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Honorable Commissioner of Patents and Trademarks, Washington, DC 20231 on the date set forth below.

1/25/90
Date of Signature and of Mail Deposit

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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

The Applicants and their attorney are aware of the following publications and information, and in accordance with 37 CFR §1.97, hereby make a record of those publications which have been identified in, or reviewed during preparation of this application.

A PTO form 1449 and copies of each publication listed thereon are enclosed, with the exception of EPO 179,979 and EPO 69,260, for which English-language abstracts are provided. The pertinence of each publication as presently understood is noted below.

Reddi, Coll. Res. 1:209-226 (1981) is understood to relate to a review of the cell biology and biochemistry of endochondral bone development, including a discussion of the developmental cascade of bone resorption and remodeling.

Sampath et al., 78 Proc. Natl. Acad. Sci. USA 12:7599-7603 (1981) is understood to relate to the dissociative extraction and reconstitution of extracellular matrix components involved in local bone differentiation.

Sampath et al., Proc. Natl. Acad. Sci. USA 80:6591-6595 (1983) is understood to relate to the bone inductive proteins from human, monkey, bovine, and rat extracellular matrix, and to a comparison of their biochemical and enzymatic characteristics.

EPO 309 241 is understood to claim a method of bone repair using an osteogenic matrix extract, and a matrix carrier of mineral and collagen.

U.S. 4,563,350 is understood to disclose a composition suitable for inductive bone implants comprising a carrier having a percentage of non-fibrillar collagen.

Deatherage et al., Collagen Rel. Res. 7:225-231 (1987) is understood to describe a delivery system for bone induction factors comprising human Type-I collagen.

Deatherage et al., Int. J. Oral Maxillofac. Surg. 17:395-399 (1988) is understood to review matrix-induced osteogenesis as understood to date, with specific reference to its use in cranio-facial surgery.

U.S. 4,795,467 is understood to disclose a composition for bone repair comprising calcium phosphate minerals and atelopeptide, reconstituted, cross-linked, fibrillar collagen.

U.S. 4,789,663 is understood to disclose a method of bone repair comprising atelopeptide, artificially-crosslinked collagen.

Spector, 2 J. Arthroplasty 2:163-177 (1987) is understood to review the state of the art of porous-coated implants as understood to date.

EPO 169 001 is understood to disclose a collagen-coated prosthesis comprising purified, atelopeptide collagen prepared from bone or skin.

U.S. 4,812,120 is understood to disclose a prosthetic dental device having an outer layer through which protrude collagen fibrils.

UK 2 178 447 is understood to disclose a fibrous or porous foam matrix for *in vitro* cell cultivation.

Strand et al., *Biotech. Bioeng.* 26:503-507 (1984) is understood to disclose a matrix for *in vitro* cell cultivation comprising microcarrier beads of DEAE or polyacrylamide.

U.S. 4,725,671 is understood to disclose atelopeptide collagen fibers for use in cell cultivation.

EPO 170 979 (abstract) is understood to disclose a drug delivery system comprising resorbable implants of reconstituted, crosslinked collagen tissue or sponge.

EPO 069 260 (abstract) is understood to disclose a sustained release vehicle comprising highly pure collagen sheets.

EPO 230 647 is understood to disclose a method of preparing a sustained release vehicle comprising atelopeptide collagen and/or gelatin.

Aspenberg et al., J. Bone Joint Surg. [Br] 70:625-627 (1988) is understood to describe experiments done on bone induction in adult monkeys.

Cook et al., Clin. Orthopaed. Rel. Res. 232:225-243 (1988) is understood to evaluate hydroxyapatite-coated titanium for use in orthopedic implant applications.

EPO 148 155 is understood to disclose purification of osteogenic factors. The matrix used to measure bone induction is allogenic demineralized bone matrix.

WO 88/00205 is understood to disclose purification of osteogenic factors. The matrix used to measure bone induction is allogenic demineralized bone matrix.

EPO 212 474 is understood to disclose purification of osteogenic factors. The matrix used to measure bone induction is allogenic demineralized bone matrix.

WO 86/00526 is understood to disclose carriers for the time-dependent release of soluble bone protein. THe carriers comprise fibrin clots or demineralized, extracted bone chips that are crosslinked or surface-coated with gelatin and/or fibrin.

EPO 182 483 is understood to disclose a conposition suitable for inductive bone implants, comprising a carrier having a percentage of non-fibrillar collagen.

U.S. 4,394,370 is understood to disclose a composition for repairing osseous defects. The composition comprises reconstituted collagen, preferably crosslinked, and demineralized bone particles or bone morphogenic protein.

U.S. 4,563,489 is understood to disclose a delivery system for bone morphogenic protein comprising polylactic acid polymer.

Glowacki et al., The Lancet 959-963 (May 2, 1981) is understood to disclose the use of allogenic, demineralized bone implants in cranial-maxillofacial reconstruction.

Urist et al., Clin. Orthoped. Rel. Res. 187:277-280 (1984) is understood to disclose a ß-tricalcium phosphate delivery system for bone morphogenic protein.

Respectfully submitted,

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January 25, 1990